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# THE UNITED STATES OF AMERICA

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**APPLICATION NUMBER:** ***60/553,966***
**FILING DATE:** ***March 18, 2004***

**By Authority of the**
**COMMISSIONER OF PATENTS AND TRADEMARKS**

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PTO/SB/16 (01-04)
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# PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

## INVENTOR(S)

| Given Name (first and middle [if any]) | Family Name or Surname | Residence (City and either State or Foreign Country) |
|---|---|---|
| ELAN | 2IV MD | RAMAT GAN, ISRAEL |

*Additional inventors are being named on the* _____ *separately numbered sheets attached hereto*

## TITLE OF THE INVENTION (500 characters max)

A DISMANTLING SYSTEM FOR A DISPOSABLE DEVICE FOR TREATING PELVIC ORGAN PROLAPSE

## CORRESPONDENCE ADDRESS

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## ENCLOSED APPLICATION PARTS *(check all that apply)*

☑ Specification *Number of Pages* 7

☑ Drawing(s) *Number of Sheets* 3

☑ Application Data Sheet. See 37 CFR 1.76

☐ CD(s), Number _____

☐ Other (specify) _____

## METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☑ Applicant claims small entity status. See 37 CFR 1.27.

☑ A check or money order is enclosed to cover the filing fees.

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$80

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☑ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____



*Respectfully submitted,*

SIGNATURE _____

TYPED or PRINTED NAME Dr. ELAN 2IV MD

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Date 15.3.04

REGISTRATION NO. _____
*(if appropriate)*
Docket Number: _____

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U.S. PTO

# FEE TRANSMITTAL for FY 2004

*Effective 10/01/2003. Patent fees are subject to annual revision.*

☑ Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** ($) 80

| *Complete if Known* | |
|---|---|
| Application Number | |
| Filing Date | MARCH 15, 2004 |
| First Named Inventor | Dr Elan Ziv |
| Examiner Name | |
| Art Unit | |
| Attorney Docket No. | |

## METHOD OF PAYMENT *(check all that apply)*

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## FEE CALCULATION

### 1. BASIC FILING FEE

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description | Fee Paid |
|---|---|---|---|---|---|
| 1001 | 770 | 2001 | 385 | Utility filing fee | |
| 1002 | 340 | 2002 | 170 | Design filing fee | |
| 1003 | 530 | 2003 | 265 | Plant filing fee | |
| 1004 | 770 | 2004 | 385 | Reissue filing fee | |
| 1005 | 160 | 2005 | 80 | Provisional filing fee | 80 |

**SUBTOTAL (1)** ($) 80

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

| | | Extra Claims | | Fee from below | | Fee Paid |
|---|---|---|---|---|---|---|
| Total Claims | | -20** = | | X | = | |
| Independent Claims | | - 3** = | | X | = | |
| Multiple Dependent | | | | | = | |

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description |
|---|---|---|---|---|
| 1202 | 18 | 2202 | 9 | Claims in excess of 20 |
| 1201 | 86 | 2201 | 43 | Independent claims in excess of 3 |
| 1203 | 290 | 2203 | 145 | Multiple dependent claim, if not paid |
| 1204 | 86 | 2204 | 43 | ** Reissue independent claims over original patent |
| 1205 | 18 | 2205 | 9 | ** Reissue claims in excess of 20 and over original patent |

**SUBTOTAL (2)** ($)

***or number previously paid, if greater; For Reissues, see above*

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description | Fee Paid |
|---|---|---|---|---|---|
| 1051 | 130 | 2051 | 65 | Surcharge - late filing fee or oath | |
| 1052 | 50 | 2052 | 25 | Surcharge - late provisional filing fee or cover sheet | |
| 1053 | 130 | 1053 | 130 | Non-English specification | |
| 1812 | 2,520 | 1812 | 2,520 | For filing a request for *ex parte* reexamination | |
| 1804 | 920* | 1804 | 920* | Requesting publication of SIR prior to Examiner action | |
| 1805 | 1,840* | 1805 | 1,840* | Requesting publication of SIR after Examiner action | |
| 1251 | 110 | 2251 | 55 | Extension for reply within first month | |
| 1252 | 420 | 2252 | 210 | Extension for reply within second month | |
| 1253 | 950 | 2253 | 475 | Extension for reply within third month | |
| 1254 | 1,480 | 2254 | 740 | Extension for reply within fourth month | |
| 1255 | 2,010 | 2255 | 1,005 | Extension for reply within fifth month | |
| 1401 | 330 | 2401 | 165 | Notice of Appeal | |
| 1402 | 330 | 2402 | 165 | Filing a brief in support of an appeal | |
| 1403 | 290 | 2403 | 145 | Request for oral hearing | |
| 1451 | 1,510 | 1451 | 1,510 | Petition to institute a public use proceeding | |
| 1452 | 110 | 2452 | 55 | Petition to revive - unavoidable | |
| 1453 | 1,330 | 2453 | 665 | Petition to revive - unintentional | |
| 1501 | 1,330 | 2501 | 665 | Utility issue fee (or reissue) | |
| 1502 | 480 | 2502 | 240 | Design issue fee | |
| 1503 | 640 | 2503 | 320 | Plant issue fee | |
| 1460 | 130 | 1460 | 130 | Petitions to the Commissioner | |
| 1807 | 50 | 1807 | 50 | Processing fee under 37 CFR 1.17(q) | |
| 1806 | 180 | 1806 | 180 | Submission of Information Disclosure Stmt | |
| 8021 | 40 | 8021 | 40 | Recording each patent assignment per property (times number of properties) | |
| 1809 | 770 | 2809 | 385 | Filing a submission after final rejection (37 CFR 1.129(a)) | |
| 1810 | 770 | 2810 | 385 | For each additional invention to be examined (37 CFR 1.129(b)) | |
| 1801 | 770 | 2801 | 385 | Request for Continued Examination (RCE) | |
| 1802 | 900 | 1802 | 900 | Request for expedited examination of a design application | |

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid **SUBTOTAL (3)** ($)

## SUBMITTED BY

(Complete *(if applicable)*)

| | | | |
|---|---|---|---|
| *Name (Print/Type)* | Dr Elan Ziv MD | *Registration No. (Attorney/Agent)* | *Telephone* +97237369261 |
| *Signature* | | *Date* | March 14, 2004 |

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# A DISMANTLING SYSTEM FOR A DISPOSABLE DEVICE FOR TREATING PELVIC ORGAN PROLAPSE.

The present invention relates generally to the field of treatment and prevention of pelvic organ prolapse in female patients. Specifically, the invention describes a dismantling system of a vaginal disposable device which is inserted into the vagina by the patient herself, allowing for an easy removal of the device.

**Inventor**: Dr Elan Ziv, MD OBGYN, Urogynecologist

## Background of the Invention

Pelvic organ prolapse is defined as a condition in which vaginal wall support is lost, and various pelvic organs prolapse into the vagina. This is a very bothering condition, though in most cases it is not a dangerous one. It might appear alone or in combination with urinary stress incontinence.

POP (Pelvic Organ Prolapse) is a very common condition in females, in which various organs, surrounding the vagina, prolapse into it. The reasons for such prolapse are numerous, mainly because the vagina has a very low tensile strength within its walls due to damage to muscles, nerves, fascias etc. There might also be a change within the collagen content, thereby causing a weaker pelvic floor. According to the older definition, prolapse may be divided into five categories, according to the organ that is sagging down (urethra, bladder, uterus, rectum and the pouch of Douglas (small bowl)), and to three grades according to the amount of descent (within the vagina, at the entrance to the vagina, protruding out of the vagina). There might be a combination of various organs prolapse at the same time, with different level of descent. The newer classification (POP-Q) takes into account other factors, such as location of the prolapse and the distance from the entrance of the vagina. There is very little data regarding the prevalence of the problem but it seems to be age related, and older women have much higher tendency towards developing some form of pelvic organ prolapse.

## Current treatment

At present – there are 2 ways of dealing with Pelvic Organ Prolapses:

1. Surgical – vaginal or abdominal
2. Use of vaginal devices (pessaries) that are inserted into the vagina and mechanically reduce the prolapse by pushing the wall aside and upwards.

Efforts to avoid surgical procedures have resulted in the development of a number of non-surgical vaginal devices, inserted into the vagina by the surgeon or the patient.

Vaginal devices are well known for their tremendous diversity in shapes and sizes. These devices are meant to prevent prolapse of the vaginal walls, with different location of pressure application.

Some of these devices tend to block all flow of urine from the bladder. Therefore, when a patient needs to urinate, the device must be removed from the vagina or must be collapsed to remove the pressure applied against the bladder neck. Trying to solve this problem, vaginal devices were developed in special shapes, without completely blocking the bladder neck so that the patient may urinate with the device in place. These devices, however, are generally large and intrusive and, therefore, are uncomfortable to wear, with low patient satisfaction and compliance. They are also relatively expensive, and therefore designed to be reusable.

There are several drawbacks of existing vaginal devices:

1. Most of them are intended to be reusable, hence they are made as resilient large bodies, made of plastic, hard rubber, or other such materials, in order to preserve their shape and function for a long time.
2. Insertion of large noncompliant bodies is sometimes difficult, painful or unpleasant, sometimes necessitating a medical practitioner.
3. Removal causes same unpleasantness, sometimes even more than insertion. The patient or the medical practitioners have to insert a finger into the vagina in order to "hook" the device and pull it out without the ability to reduce its dimensions for a more comfortable passage. In order to avoid insertion of a finger, a hook like extractor was developed (US patent D404127) was developed but has never been in use.

4. Most reusable devices are meant to remain in the vagina for prolonged periods of time, thereby causing irritations, pressure ulcers, infections, foul smelling discharge, etc.
5. Such reusable devices have a long standing bad reputation among patients and medical practitioners for being unpleasant, causing infectious discharge and foul odor, and being associated with disability and old age.
6. Some reusable devices are meant to be inserted daily by the patient, and to be removed after several hours, by means of pulling a string or with a finger, to be cleaned for re-use, and to be kept in certain conditions prior to following insertion. Some patients are reluctant to touch their selves in such intimate parts of their bodies, or disgusted to clean the device, hence their reluctance to use it.

Vaginal devices may cause three main side effects:

1. **Infections**-any foreign material, anywhere in the body, may become infected by several kinds of organisms, and cause formation of a foul smelly discharge. Reusable devices are certainly prone to cause such infections, but also, less frequently, disposable ones. In order to prevent such infections, devices should be:
   - disposable
   - used for a limited length of time, in order to prevent organism from growing, and to prevent damage, by vascular pressure, to the vaginal wall.
   - made in a way that will allow vaginal or cervical normal secretions to flow out of the body
   - made of certain known materials that would not permit growth of organisms.
2. **Toxic Shock Syndrome (TSS)** is a condition, described some years ago, in which abundant growth of Staphylococus Aureus, a bacteria that utilizes the cellulose within sanitary menstrual tampons, released large amounts of toxin. That toxin caused a collapse of vital body systems, forming a dangerous condition. In order to overcome this, sanitary tampons do not contain cellulose anymore, and vaginal devices, as described earlier, should be made of materials that would not permit the growth of bacteria, and allow for discharge flow. This is best done by using properly made disposable devices.

3. **Pressure Necrosis** – prolonged pressure on the vaginal sidewalls may cause pressure on blood vessels with resultant necrosis, bleeding and infections. This might be prevented by using disposable devices only, for a predetermined length of time.

5

## The invention

This dismantling device was developed following the invention of a previous device, intended to be inserted into the vagina with an applicator. The device is intended to be applied into the vagina with an applicator much like the insertion of a regular menstrual tampon .After insertion, the device should expand significantly to the predefined shape and size, thereby exerting predefined appropriate pressure on both lateral vaginal walls, pushing them aside. The apex of the vagina shall be pushed upwards at the same time. That expansion of the device shall eventually create linear stretching of the anterior & posterior vaginal walls, while creating a new shape of intra-vaginal hollow (rectangle). The device may be left inside the vagina for several hours. Removal for disposal will occur while pulling a string and collapsing the device to a much smaller size.

As with other devices of the prior art, this device has a ring or rectangular shape. Removal of such a large body through a small dimension vaginal introitus might be extremely painful and uncomfortable, hence the need for designing such a specific dismantling system.

This new inventions brings about a system for collapsing a large body into a much smaller one which will allow its immediate removal.

The invention will now be described with reference to accompanying drawings:

- FIG.1A is a front view of the dismantling system in the device.
- FIG.1B is a side view of the dismantling system in the device.
- FIG.1C is a perspective view of the dismantling system in the device.
- FIG.2A is a front view of the open dismantling system in the device.
- FIG.2B is a side view of the open dismantling system in the device.
- FIG.2C is a perspective view of the open dismantling system in the device.
- FIG.3 is a front view of the conic shape of the device when the collapse system pulls it out.

The dismantling system has two phases:

- Closed (FIG 1)
- Opened (FIG 2)

Figures 1A+1B+1C show the device in its front, side & perspective views. A small dismantling ring (6,14) is attached in a 90 degrees fashion to the main body of the

device (10,13), within two collapsing sites (18L, 18R), which are small indentation located on its inner surface, close to its lowest margin. These two indented sites enable to contain the dismantling ring without harming the devices integrity and strength. Removal string (12, 16) is attached to the dismantling ring. Connecting string (8) statically connects between the device (13) and the dismantling ring (14). Since the dismantling ring is located within the indentation, the mechanical strength of the device remains unchanged, and its intended task is fulfilled. This phase remains as long as there is no pull of the string.

Figures 2A+2B+2C show the beginning of the opened phase – the system after first pull of the string as a first step in removal of the device from the vagina. When string (16) is pulled, the dismantling ring (14) is moved away from its two indented sites (18R, 18L), and hangs away from the device itself, connected to it by the connecting string (20), in a lower position within the vagina.

FIG 3 shows a more advanced pull of the string. At this stage, the two indentation sites (22) collapse as a result of lower strength and the device becomes narrow in its lower part (conical), thereby allowing for comfortable and easy removal (still as one unit) from the vagina, for disposal.

The invention has in its basic concept the following features:

- Being a disposable device.
- Easy & comfortable removal.
- Being comfortable to wear.
- Being hygiene & odorless
- Being a familiar procedure to most female patients – as inserting a menstrual tampon.
- Being removed by the patient herself, in a no-self-touch technique, with the device collapsing and becoming of small size for painless removal.
- Being of high availability, easy to get everywhere, sold as an Over the Counter (OTC) device.
- Being of low cost.
- Having complete confidentiality, as with the use of menstrual tampons.
- Having the ability to be removed instantly when needed.
- The system does not influence performance of the device itself.
- The system helps anchoring the device within the vagina.
- The device is removed as one unit and does not require division.

**Alternative embodiments of the invention.**

- Dismantling rings may be manufactured in different sizes
- Dismantling rings may be manufactured in different strengths
- It may be made of many flexible materials, such as plastics, cardboard, etc.
- Collapsing indentations may be added to the device.
- Collapsing indentation sites may be changed.

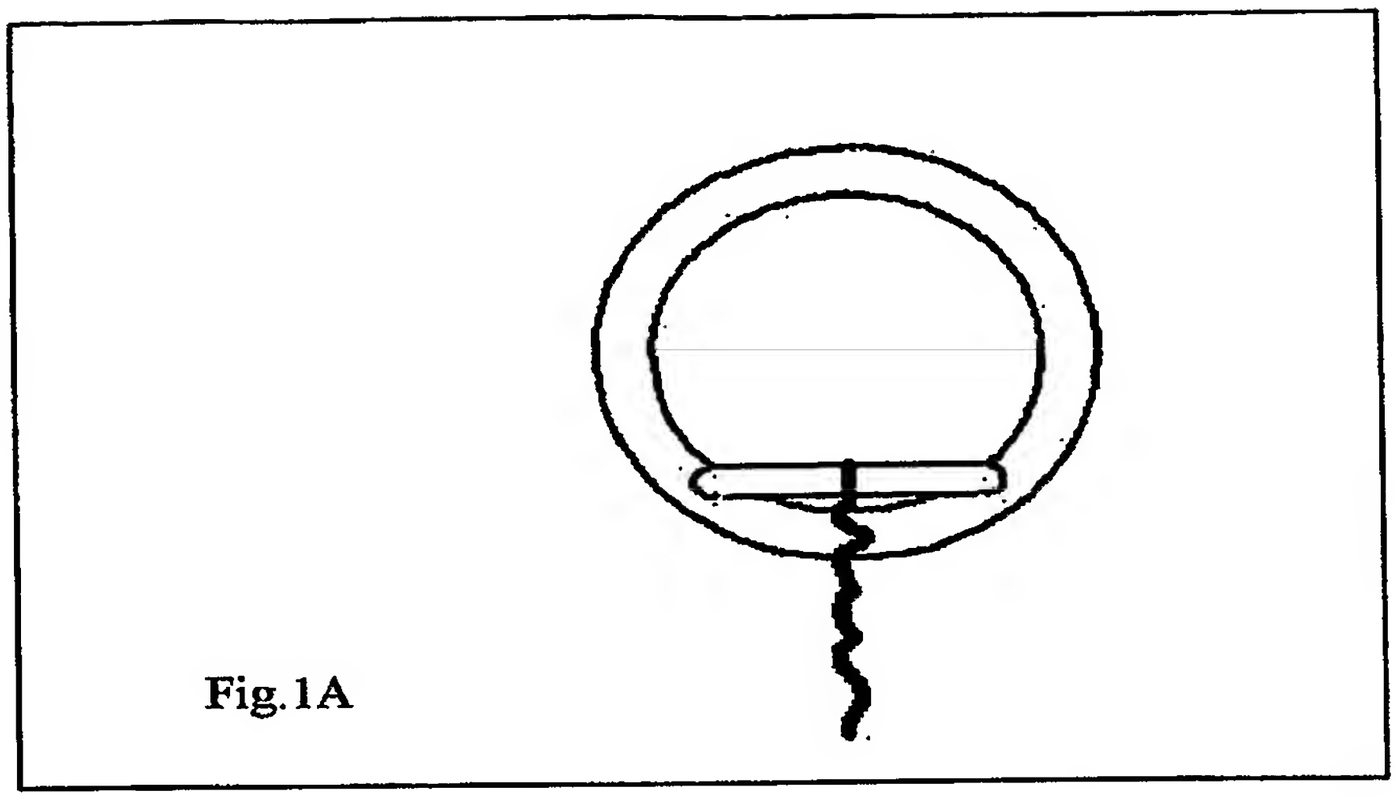

Fig.1A

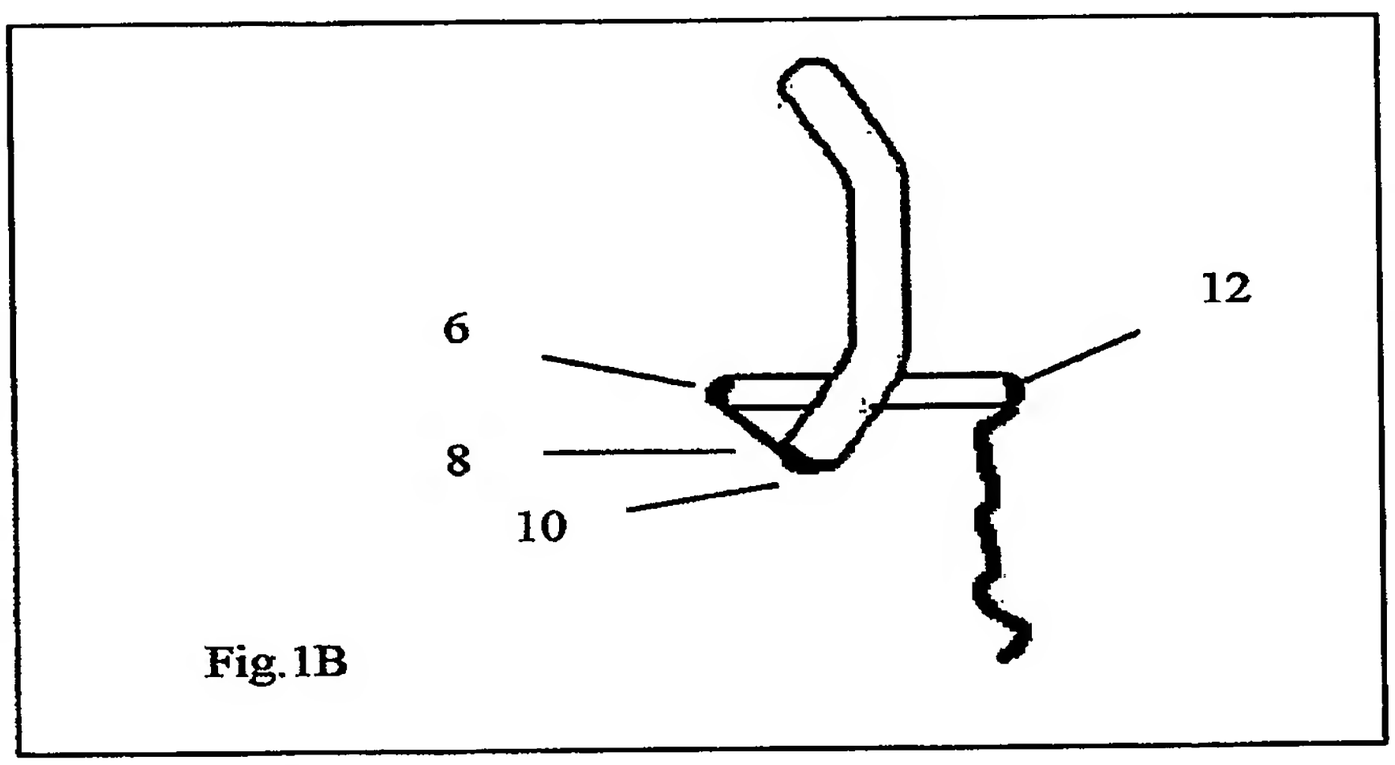


Fig.1B

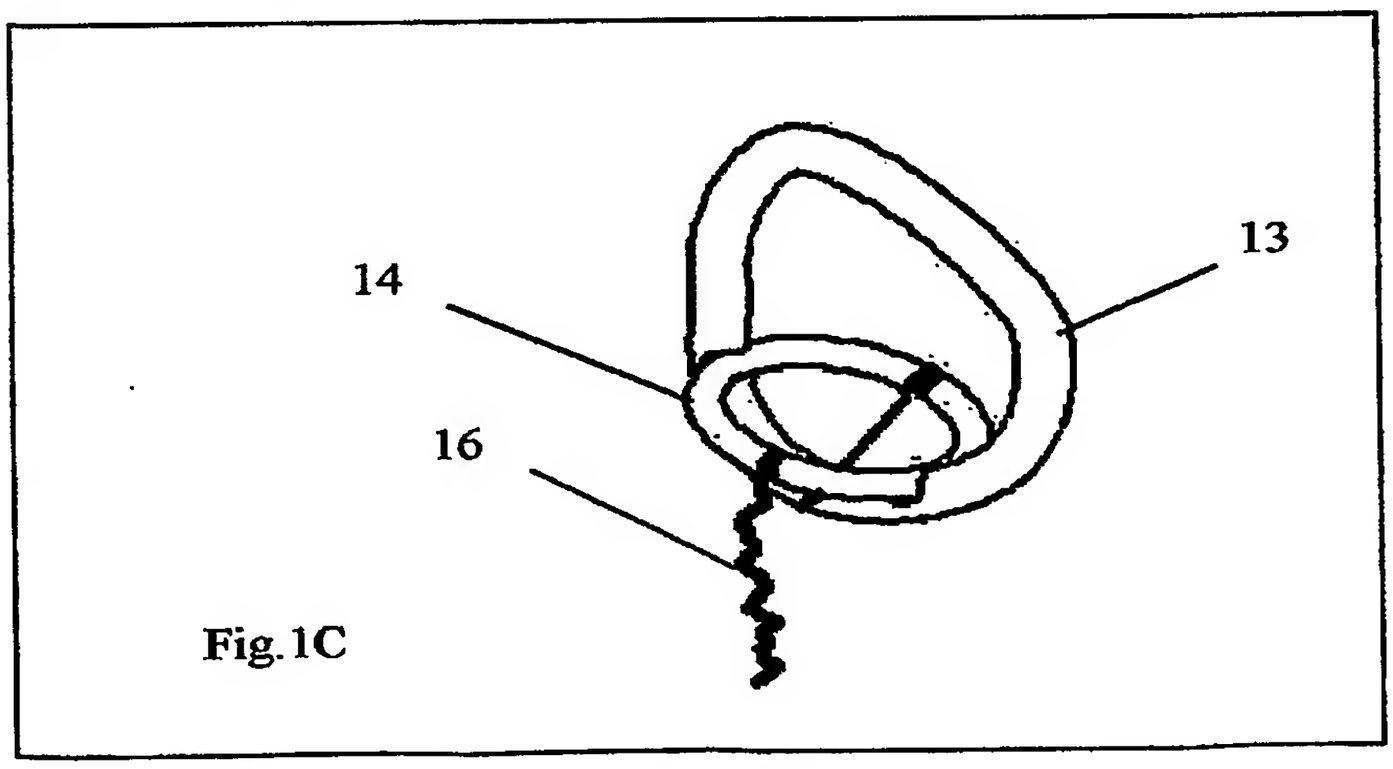


Fig.1C



BEST AVAILABLE COPY

"A dismantling system for a disposable device for treating pelvic organ prolapse"
Dr Elan Ziv, MD OBGYN, Urogynecologist

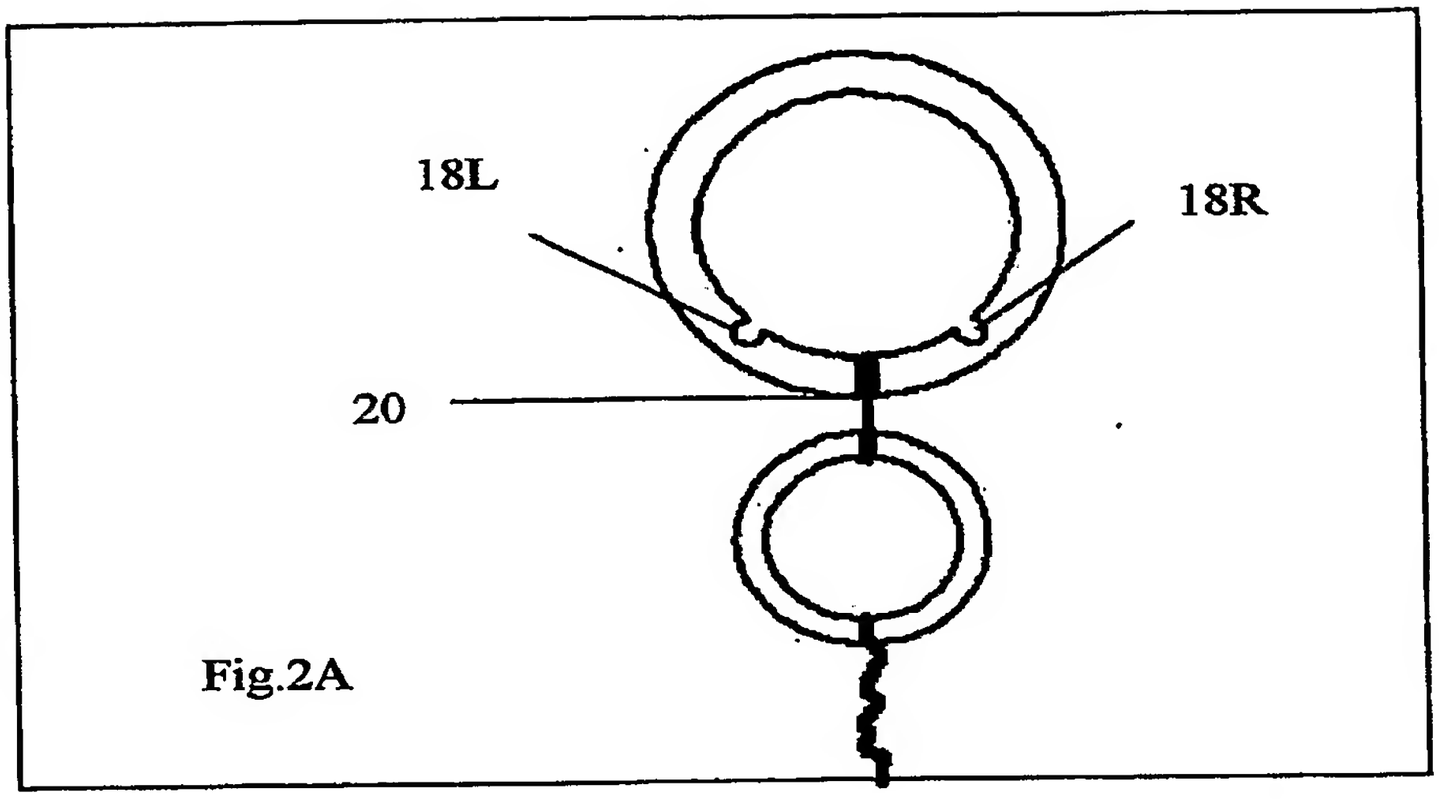


Fig.2A

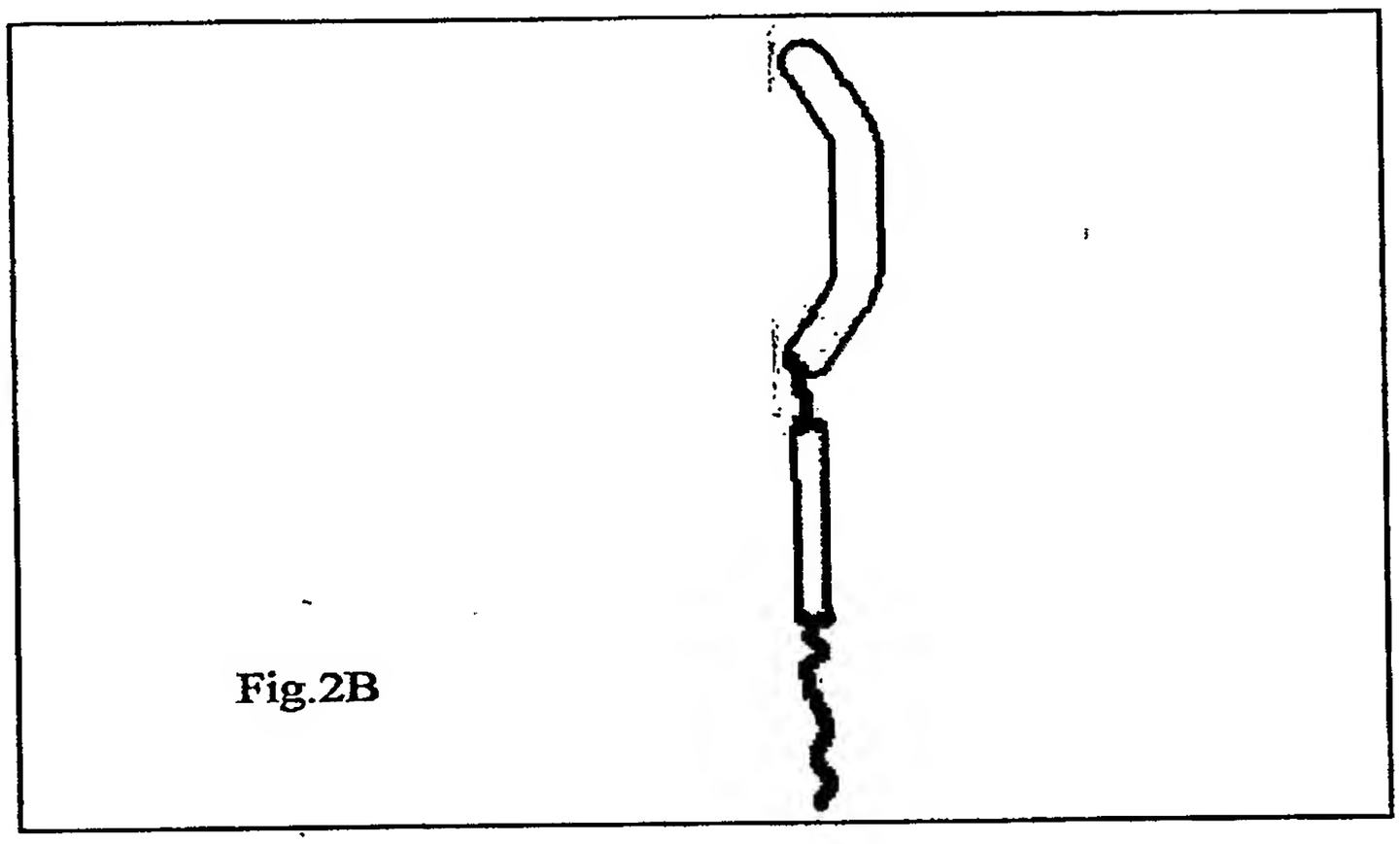

Fig.2B

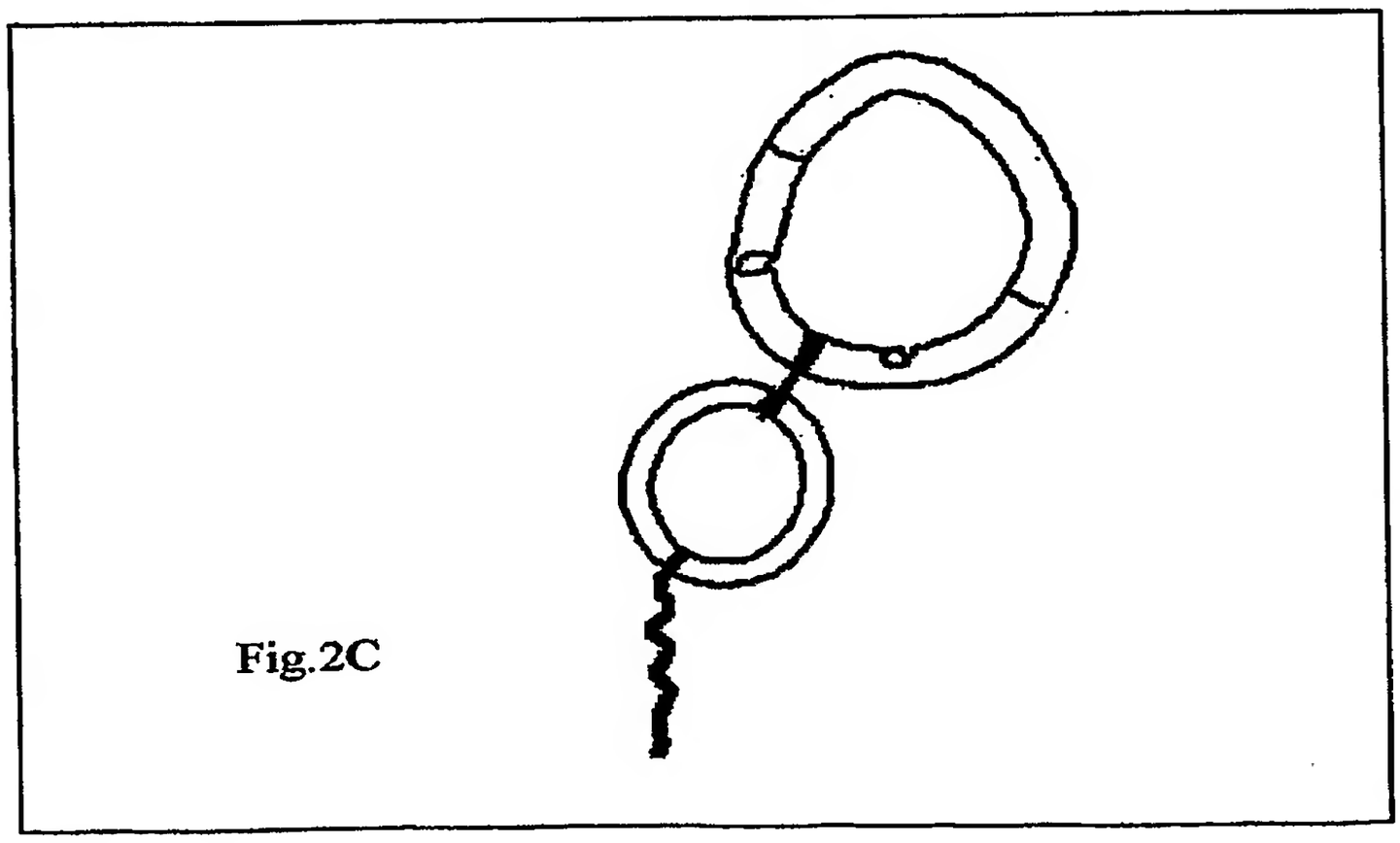

Fig.2C

"A dismantling system for a disposable device for treating pelvic organ prolapse"
Dr Elan Ziv, MD OBGYN, Urogynecologist

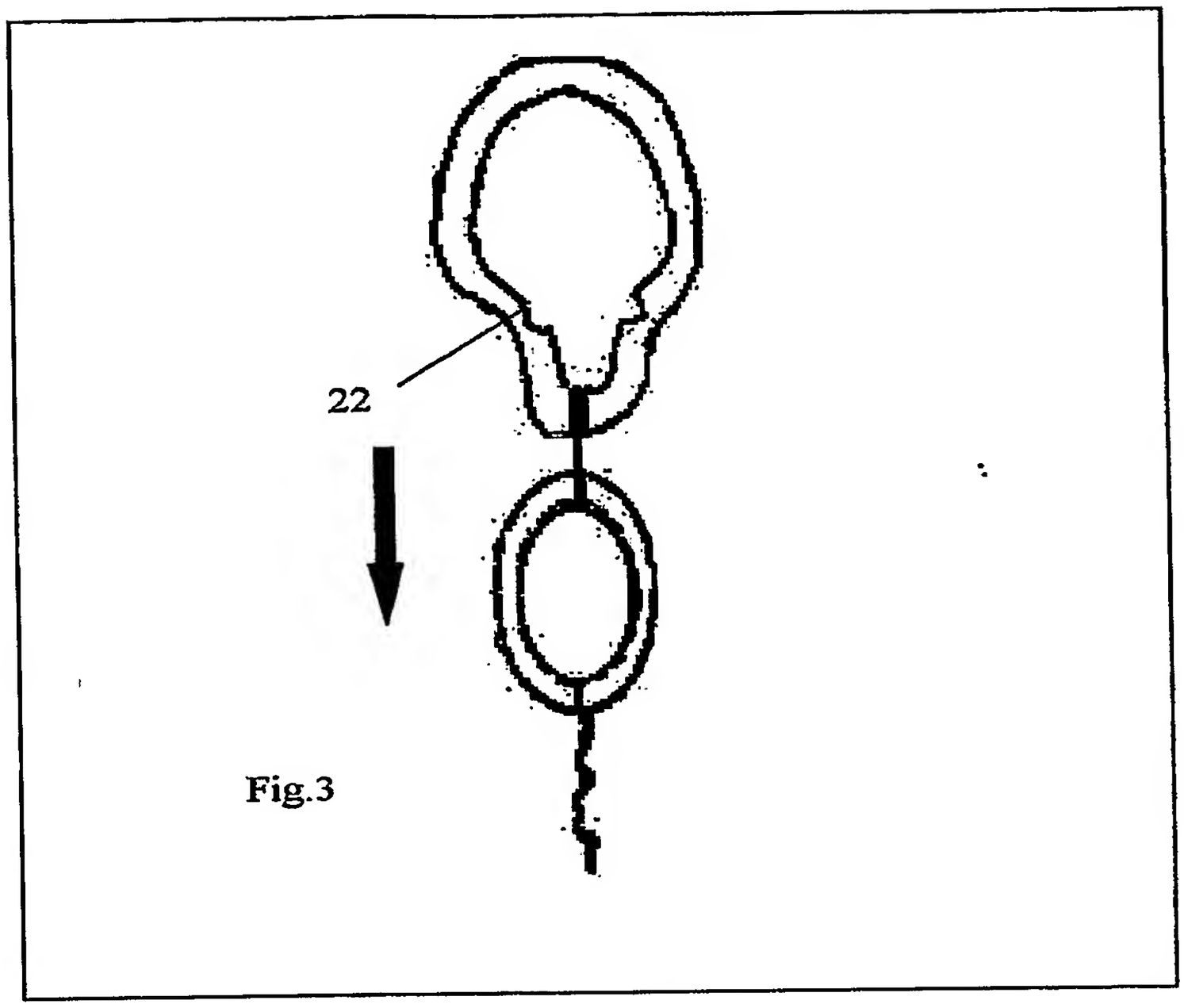


Fig.3

"A dismantling system for a disposable device for treating pelvic organ prolapse"
Dr Elan Ziv, MD OBGYN, Urogynecologist